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10/815,425

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EXAMINER

POLANSKY, GREGG

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/815,425 | Applicant(s) HAMMOCK ET AL. | |
| | Examiner Gregg Polansky | Art Unit 1614 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 9-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action supersedes the restriction requirement of 2/01/2006 and is necessitated by Applicants' claim amendments of 11/13/2006.
2. Applicants' arguments, filed 11/13/2006, with respect to Claims 9, 10, 14-18, 25, 26, and 30-34 are noted. A response to the arguments will follow Applicants' election of a group and species defined in this restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 9-18 and 25-34, drawn to a method of inhibiting progression of an obstructive pulmonary disease, an interstitial lung disease, or asthma, with an inhibitor of soluble epoxide hydrolase, and optionally, a cis-epoxyeicosantrienoic acid (EET), classified in various subclasses of class 514, depending on the inhibitor and EET contemplated.
Election of this invention requires species elections as set forth below.
 - II. Claims 19-24, drawn to a method of inhibiting progression of an obstructive pulmonary disease, an interstitial lung disease, or asthma, with a nucleic acid that inhibits expression of soluble epoxide hydrolase, and optionally, a cis-epoxyeicosantrienoic acid, classified in class 514, subclass 44, for example.
Election of this invention requires species elections as set forth below.

- III. Claims 35-40, drawn to a method of inhibiting progression of an obstructive pulmonary disease, an interstitial lung disease, or asthma, with a nucleic acid that inhibits expression of a gene encoding a soluble epoxide hydrolase, and a cis-epoxyeicosantrienoic acid, classified in class 536, subclass 24.5, for example.

Election of this invention requires species elections as set forth below.

- IV. Claims 41-50, drawn to a method of reducing infiltration of neutrophils into the lungs of a patient suffering from an obstructive pulmonary disease, an interstitial lung disease, or asthma, with an inhibitor of soluble epoxide hydrolase, and optionally, a cis-epoxyeicosantrienoic acid (EET), classified in various subclasses of class 514, depending on the inhibitor and EET contemplated.

Election of this invention requires species elections as set forth below.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Invention I is drawn to a method of inhibiting progression of a condition using an inhibitor of soluble epoxide hydrolase that is a small molecule, urea based compound. Invention II is drawn to a method of inhibiting progression of a condition using a nucleic acid that inhibits production of

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soluble epoxide hydrolase. Invention III is drawn to a method of inhibiting progression of a condition using a nucleic acid that inhibits a gene encoding a soluble epoxide hydrolase. Invention IV is drawn to a method of reducing infiltration of neutrophils into the lungs of a patient. Clearly, these four inventions have different designs, modes of operation, and effects.

Restriction for examination purposes as indicated is proper because the inventions listed in this action are independent or distinct for the reasons given above, and there would be a serious search and examination burden if restriction were not required. Further, one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

3. This application contains claims directed to the following patentably distinct species:

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- a. Inhibitors of soluble epoxide hydrolase,
- b. A cis-epoxyeicosantrienoic acid (EET),
- c. A **specific** nucleic acid that inhibits production of soluble epoxide hydrolase, and
- d. A **specific** nucleic acid that inhibits expression of a gene encoding soluble epoxide hydrolase.
- e. A pulmonary disease selected from the group consisting of an obstructive pulmonary disease, an interstitial lung disease, or asthma (**Applicants must elect one**).

Inventions I-IV require a species election from "e" above in addition to the following. If inventions I or IV are elected, Applicants must elect a specific species from "a" and "b" above. If invention II is elected, Applicants must elect a specific species from "b" and "c" above. If invention III is elected, Applicants must elect a specific species from "b" and "d" above.

The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of

search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

4. **Applicant is advised that, to be complete, the reply to this requirement must include (i) an election of an invention and species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected inventions and species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the inventions and species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of invention or species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the invention or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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or species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention or species, respectively.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregg Polansky whose telephone number is (571) 272-9070. The examiner can normally be reached on Mon-Thur 8:30 A.M. - 7:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gregg Polansky

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER
10/26/07